

Recognized Standards, Recognition List Number: 040” will be available at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/ucm123792.htm>. You may access “Guidance on the Recognition and Use of Consensus Standards,” and the searchable database for “FDA Recognized Consensus Standards” at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards>.

VII. Submission of Comments and Effective Date

Interested persons may submit either electronic comments regarding this document to <http://www.regulations.gov> or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at <http://www.regulations.gov>. FDA will consider any comments received in determining whether to amend the current listing of modifications to the list of recognized standards, Recognition List Number: 040. These modifications to the list of recognized standards are effective upon publication of this notice in the **Federal Register**.

Dated: August 10, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015-19991 Filed 8-13-15; 8:45 am]

BILLING CODE 4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2009-D-0386]

Establishing the Performance Characteristics of In Vitro Diagnostic Devices for the Detection or Detection and Differentiation of Human Papillomaviruses; Draft Guidance for Industry and Food and Drug Administration Staff: Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled “Establishing the Performance Characteristics of In Vitro Diagnostic Devices for the Detection or Detection and Differentiation of Human

Papillomaviruses.” This draft guidance provides recommendations to facilitate study designs to establish the performance characteristics of in vitro diagnostic devices (IVDs) intended for the detection, or detection and differentiation, of human papillomaviruses (HPVs). This draft guidance is not final nor is it in effect at this time.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment of this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance November 12, 2015.

ADDRESSES: An electronic copy of the guidance document is available for download from the Internet. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance. Submit written requests for a single hard copy of the draft guidance document entitled “Establishing the Performance Characteristics of In Vitro Diagnostic Devices for the Detection or Detection and Differentiation of Human Papillomaviruses” to the Office of the Center Director, Guidance and Policy Development, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your request.

Submit electronic comments on the draft guidance to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT:

Natalia Comella, Center for Devices and Radiological Health, Food and Drug Administration, New Hampshire Ave., Bldg. 66, Rm. 4536, Silver Spring, MD 20993-0002, 301-796-6226, Natalia.Comella@fda.hhs.gov, or Marina V. Kondratovich, Center for Devices and Radiological Health, Food and Drug Administration, New Hampshire Ave., Bldg. 66, Rm. 4672, Silver Spring, MD 20993-0002, 301-796-6036, Marina.Kondratovich@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

This draft guidance provides recommendations to facilitate study designs to establish the performance

characteristics of IVDs intended for the detection, or detection and differentiation, of HPVs. These devices are used either in conjunction with cervical cytology to aid in screening for cervical cancer or as first-line primary cervical cancer screening devices. These devices include those that detect a group of HPV genotypes, particularly high risk HPVs, as well as devices that detect more than one genotype of HPV and further differentiate among them to indicate which genotype of HPV is present or which genotypes of HPV are present.

When finalized, this draft guidance is expected to provide detailed information on the types of studies the FDA recommends to support a premarket application for these devices. This draft guidance specifically addresses devices that qualitatively detect HPV nucleic acid from cervical specimens, but many of the recommendations will also be applicable to devices that detect HPV proteins. The draft guidance is limited to studies intended to establish the performance characteristics of in vitro diagnostic HPV devices that are used in conjunction with cervical cytology for cancer screening or as first-line primary cervical cancer screening devices. This draft guidance does not address HPV testing from non-cervical specimens such as pharyngeal, vaginal, penile, or anal specimens, or testing for susceptibility to HPV infection. It does not address quantitative or semi-quantitative assays for HPV.

II. Significance of Guidance

This draft guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on evaluating the performance characteristics of IVDs intended for the detection, or detection and differentiation, of HPVs. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statute and regulations.

III. Electronic Access

Persons interested in obtaining a copy of the draft guidance may do so by downloading an electronic copy from the Internet. A search capability for all Center for Devices and Radiological Health guidance documents is available at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm>. Guidance documents are also available at <http://www.regulations.gov>. Persons

unable to download an electronic copy of “Establishing the Performance Characteristics of In Vitro Diagnostic Devices for the Detection or Detection and Differentiation of Human Papillomaviruses” may send an email request to CDRH-Guidance@fda.hhs.gov to receive an electronic copy of the document. Please use the document number 1740 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR part 814 have been approved under OMB control number 0910–0231; the collections of information in 21 CFR part 812 have been approved under OMB control number 0910–0078; the collections of information in 21 CFR parts 801 and 809 have been approved under OMB control number 0910–0485; and the collections of information in the guidance document entitled “Informed Consent For In Vitro Diagnostic Device Studies Using Leftover Human Specimens That Are Not Individually Identifiable” have been approved under OMB control number 0910–0582.

V. Comments

Interested persons may submit either electronic comments regarding this document to <http://www.regulations.gov> or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at <http://www.regulations.gov>.

Dated: August 10, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–19983 Filed 8–13–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Advisory Commission on Childhood Vaccines; Notice of Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), notice is hereby given of the following meeting:

Name: Advisory Commission on Childhood Vaccines (ACCV).

Date and Time: September 3, 2015, 9:00 a.m. to 4:30 p.m. EDT.

Place: Parklawn Building (and via audio conference call and Adobe Connect), 5600 Fishers Lane, Room 10–65, Rockville, MD 20857.

The ACCV will meet on Thursday, September 3, 2015, from 9:00 a.m. to 4:30 p.m. (EDT). The public can join the meeting by:

1. (In Person) Persons interested in attending the meeting in person are encouraged to submit a written notification to: Annie Herzog, DVIC, Healthcare Systems Bureau (HSB), Health Resources and Services Administration (HRSA), Room 11C–26, 5600 Fishers Lane, Rockville, Maryland 20857 or email: aherzog@hrsa.gov. Since this meeting is going to be held in a federal government building, attendees will need to go through a security check to enter the building and participate in the meeting. Written notification is encouraged so a list of attendees can be provided to Annie Herzog to make entry through security quicker. Persons may attend in person without providing written notification, but their entry into the building may be delayed due to security checks and the requirement to be escorted to the meeting by a federal government employee. To request an escort to the meeting after entering the building, call Mario Lombre at 301–443–3196. The meeting will be held at the Parklawn Building, 5600 Fishers Lane, Room 10–65, Rockville, Maryland 20857.

2. (Audio Portion) The conference Phone Number is 877–917–4913. When calling, provide the following information:

Leaders Name: Dr. A. Melissa Houston.

Password: ACCV.

3. (Visual Portion) Connect to the ACCV Adobe Connect Pro meeting using the following URL: <https://hrsa.connectsolutions.com/accv/> (copy and paste the link into your browser if it does not work directly, and enter as a guest). Participants should call and connect 15 minutes prior to the meeting in order for logistics to be set up. If you have never attended an Adobe Connect meeting, please test your connection using the following URL: https://hrsa.connectsolutions.com/common/help/en/support/meeting_test.htm and get a quick overview by following URL: http://www.adobe.com/go/connectpro_overview. Call (301) 443–6634 or send an email to aherzog@hrsa.gov if you are having trouble connecting to the meeting site.

Agenda: The agenda items for the September 2015 meeting will include, but are

not limited to: updates from ACCV Adult Immunization Workgroup, the Division of Injury Compensation Programs (DICP), Department of Justice (DOJ), National Vaccine Program Office (NVPO), Immunization Safety Office (Centers for Disease Control and Prevention), National Institute of Allergy and Infectious Diseases (National Institutes of Health), and Center for Biologics, Evaluation and Research (Food and Drug Administration). A draft agenda and additional meeting materials will be posted on the ACCV Web site (<http://www.hrsa.gov/vaccinecompensation/accv.htm>) prior to the meeting. Agenda items are subject to change as priorities dictate.

Public Comment: Persons interested in providing an oral presentation should submit a written request, along with a copy of their presentation to: Annie Herzog, DICP, Healthcare Systems Bureau (HSB), Health Resources and Services Administration (HRSA), Room 11C–26, 5600 Fishers Lane, Rockville, Maryland 20857 or email: aherzog@hrsa.gov. Requests should contain the name, address, telephone number, email address, and any business or professional affiliation of the person desiring to make an oral presentation. Groups having similar interests are requested to combine their comments and present them through a single representative. The allocation of time may be adjusted to accommodate the level of expressed interest. DICP will notify each presenter by email, mail, or telephone of their assigned presentation time. Persons who do not file an advance request for a presentation, but desire to make an oral statement, may announce it at the time of the public comment period. Public participation and ability to comment will be limited to space and time as it permits.

For Further Information Contact: Anyone requiring information regarding the ACCV should contact Annie Herzog, DICP, HSB, HRSA, Room 11C–26, 5600 Fishers Lane, Rockville, Maryland 20857; telephone (301) 443–6593, or email: aherzog@hrsa.gov.

Jackie Painter,

Director, Division of the Executive Secretariat.

[FR Doc. 2015–20136 Filed 8–13–15; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection

Activities: Submission to OMB for Review and Approval; Public Comment Request

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice.

SUMMARY: In compliance with Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the Health Resources and Services Administration (HRSA) has submitted an Information